

Rejection Under 35 USC § 112, first paragraph

Claim 8 stands rejected under 35 USC § 112, first paragraph, allegedly because the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. The rejection is traversed.

The Examiner states that the specification fails to enable one of skill in the art how to search and evaluate substances effective for prevention or therapy of bone disorders. Applicants respectfully disagree with the Examiner's position, however claim 8 has been cancelled and will be pursued in a divisional application. Withdrawal of the rejection is earnestly solicited.

Rejection Under 35 USC § 112, second paragraph

Claim 6 stands rejected under 35 USC § 112, second paragraph.

The rejection is traversed. Reconsideration and withdrawal of the rejection is earnestly solicited.

Claim 6 has been cancelled, thus obviating this rejection. Withdrawal of the rejection is earnestly solicited.

Rejection Under 35 USC § 112, fourth paragraph

Claim 3 stands rejected under 35 USC § 112, fourth paragraph, as being improper dependent form. The rejection is traversed.

Claim 3 has been cancelled, thus obviating this rejection.

Rejection Under 35 USC § 102(b)

Claims 1-7 stands rejected under 35 USC § 102(b) as being clearly anticipated by Gomi et al. or Michalevicz. The rejection is traversed.

Gomi et al. reports antitumor activity of ReIFN- γ and ReIFN- β against human osteosarcoma. In this paper, osteosarcoma means a tumor originating from bone tissue, and it does not mean a tumor-related bone disorder.

On the contrary, the present invention is not directed to the antitumor activity of IFN- β , but is directed to a method where for example, IFN- β is employed to restore fractured bone tissue caused by bone metastasis of a tumor originating from tissues other than bone.

Michalevicz teaches that IFN- β has an erythropoietic effect on the growth of progenitor cells from individuals suffering from several diseases with a very low production of red blood cells (column 2, lines 24-28). Such a disorder is a malfunction of bone marrow, and is a blood disease which can be easily diagnosed by the test of peripheral blood.

It should be mentioned that bone tissue and bone marrow are allotted quite a different function. Bone is a hard supporting frame which supports the body and protects the internal organs against external forces, while the bone marrow is a soft organization which produces blood cells. Accordingly, the disorders which appear in bone versus bone marrow are completely

different. This is supported from the fact that the exemplified diseases shown in Michalevycz and in the present invention are quite different. The Examiner states that Michalevycz teaches using IFN- β for CML (a tumor related bone disorder) and rheumatoid arthritis. It is incorrect to refer to CML (Chronic Myeloid Leukemia) as a tumor related bone disorder, for the reasons mentioned in the preceding paragraph. Rather, it is related to a bone marrow related disorder. Moreover, the Examiner's attention is directed to claim 10 of Michalevycz where anemia caused by rheumatoid arthritis is claimed and not rheumatoid arthritis, per se.

Accordingly, the present claims are not anticipated by Gomi et al. or Michalevycz. Withdrawal of the rejection is earnestly solicited.

Claims 1 and 3-4 stands rejected under 35 USC § 102(b) as being clearly anticipated by Lyndon et al. The rejection is traversed.

Claims 1 and 3-4 have been cancelled, thus obviating this rejection. Withdrawal of the rejection is earnestly solicited.

In view of the foregoing amendments and remarks, claims 7 and 9-11 define patentable subject matter. A Notice of Allowance is earnestly solicited.

If the Examiner has any questions concerning this application, he is requested to contact the undersigned, at (703) 205-8000 in the Washington, D.C. area.

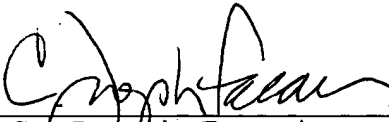
Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants respectfully petitions for a three (3) month(s) extension of time for filing a reply in connection with the present application and the required fee of \$950.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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